

## **Exhibit 1**

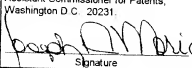
APPLICATION FOR UNITED STATES LETTERS PATENT

for

INFECTION-BLOCKING DENTAL IMPLANT

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EXPRESS MAIL MAILING LABEL
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DATE OF DEPOSIT January 3, 1997
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## INFECTION-BLOCKING DENTAL IMPLANT

### **CROSS REFERENCES TO RELATED APPLICATIONS**

This is a complete application claiming the benefit of copending Provisional Patent Application Serial No. 60/009,592 filed January 4, 1996, and is also a continuation-in-part of copending application Serial No. 08/607,903 filed February 27, 1996.

### **5 FIELD OF THE INVENTION**

This invention relates to dental implants intended for insertion in a hole provided in living jawbone for eventual support of artificial teeth. It is illustrated as realized in a cylindrical dental implant having a screw thread or screw threads on its outer surface, but it is not limited to that type of implant, and is applicable to all types of implants which share the general characteristic that while they are fitted into the living jawbone they extend out of it through the overlying gingival into the mouth wherein they support artificial teeth.

### **BACKGROUND OF THE INVENTION**

The part of a dental implant that is in the living jawbone should have a roughened surface confronting the host bone for bonding with the bone, and the part of the same  
15 implant that is exposed in the mouth should have a smooth surface because a rough surface in that location might provide a site where bacteria can attach and proliferate. For hygienic reasons the exposed surfaces of the implant should be smooth, while for osseointegration purposes the surfaces of the implant confronting the host bone should be rough. Experience over many years has taught dentists practicing implantology that approximately eighteen  
20 months after an implant has been successfully placed in the jawbone of a patient and is performing its task of supporting artificial dentition, the bone surrounding the implant immediately beneath the overlying gingival tissue will in most cases be found to have receded a small distance, exposing to the soft tissue a portion of the roughened surface of the implant which had been in bone. This phenomenon is illustrated in a book by  
25 Branemark, Zarb & Albrektsson entitled "Tissue-Integrated Prostheses" 1985, p56, Fig. 1-46. This event, occurring as it does beneath the gum tissue surrounding an artificial tooth, is not immediately visible. In spite of the most diligent hygienic practice, it presents the danger that bacteria which succeed in penetrating between the tooth and its surrounding tissue may

attach themselves to the roughened surface, and there proliferate, and bring about an infection putting the implant and the tooth it supports in danger of failure.

In U.S. 4,988,299 an implant is disclosed which has a threaded portion and a smooth neck portion. No reference is made to roughening of the threaded portion or how smooth the neck portion should be. The neck portion is defined by having a diameter between the "core" diameter of the threaded portion and the outer diameter of the threads and it is disclosed to have a curved surface. The neck portion is said to have an axial length exceeding the settlement in bone level and it is intended to avoid exposure of the threads.

#### SUMMARY OF THE INVENTION

The present invention relates to an implant which is roughened to improve osseointegration with the bone but which does not provide a surface which can facilitate infection.

Observations based on practical experience of one of the present inventors over the past ten years or more have revealed that the recession described in the above-mentioned book tends to stop at the level where the implant places a load on the host bone. In a screw-type implant this level is approximately the beginning of the first turn of the screw thread near the gingival end of the implant. However, these observations also indicate that the stopping level is not precisely the same in all cases, and that in some cases the first thread may be exposed. At times, more than one thread is exposed, perhaps up to three threads

According to the invention as illustrated in the accompanying drawings, the portion of the implant which has a roughened surface is limited to that portion which can be expected to remain in contact with the host bone after the expected bone recession has taken place. The head portion of the implant and the immediately-adjacent part of the heretofore roughened portion, including the initial part of the screw threads, are made smooth. Preferably one to three threads will be left smooth, not roughened. Typically, a length of about 3mm below the top surface of the implant will be left smooth and not roughened with the remainder of the implant. Because the amount of bone that recedes will vary with different patients, one or more smooth threads may remain permanently in the bone along with the roughened threads. Although these smooth threads may not load

the bone to the same degree as the roughened threads, nevertheless the smooth threads will still add significantly to the bone loading.

Since the exact amount of bone recession that will occur in a given patient cannot be determined in advance of the event with precision, the invention is useful to minimize the danger of infection from this source, that is, to block the infection. Good hygienic practice will continue to be required of the patient. With the invention, such good practice can be expected to be more fruitful than heretofore.

#### BRIEF DESCRIPTION OF THE DRAWINGS

The invention is described in greater detail with reference to the accompanying drawings, in which:

**FIG. 1** is a side elevation of a dental implant according to the invention; and

**FIG. 2** is an end view of the dental implant of FIG. 1.

#### DETAILED DESCRIPTION OF THE INVENTION

The implant 10 has a head portion 12, a neck portion 14 and a main body 16 which is roughened on its outer surface in the region 18. Such implants are normally machined from titanium or a titanium alloy and are smooth, until a portion is roughened to facilitate osseointegration with bone. The head portion 12, the neck portion 14, and a small region 20 of the main body 16 immediately adjacent the neck portion, encompassing the first to third thread turns, are smooth. To achieve this result the portions of the implant intended to remain smooth during and after the roughening procedure may be covered during that procedure. For example, if the roughening procedure includes an acid-etching step or steps, these parts may be covered with a suitable wax prior to immersing the implant in the etching acid. A preferred method of roughening the surface is disclosed in copending U. S. patent application Serial No. 08/607,903 mentioned above and incorporated by reference herein. The process has two steps, the first being removal of native oxide from titanium by contact with an aqueous hydrofluoric acid solution, followed by etching with a mixture of sulfuric and hydrochloric acids.

When the implant 10 is first installed in a bore prepared for it in a patient's jawbone, the implant is buried in bone up to and including the head portion 12, to the level indicated by line A - A in figure 1. The healing phase then begins, during which new bone is formed

close to the immobile, resting implant, and the implant will remain buried in the bone, up to the head portion. All the implant, including the neck portion 12, will confront the host bone in the early part of the healing phase. Thereafter when the implant is loaded and the remodeling phase begins (overlapping the healing phase) during exposure to masticatory forces, the newly formed bone remodels under the applied load until, after about eighteen months, a steady state is achieved. In this state the anchoring bone will be found to have undergone a reduction in height (bone recession) immediately adjacent the implant. The amount of this recession can vary from case to case, between the level indicated by the solid curved lines 30 and the level indicated by the broken curved lines 32, for example, exposing the head portion 12, the neck portion 14 and some or all of the immediately adjacent region 20 of the threaded main body 16. In some cases region 20 may extend further, up to about the third thread. Another way to define regions 14 and 20 is that roughening of the implant begins about 3mm below the upper flat surface 15 of the implant 10, which receives connecting parts of the dental restoration.

According to the invention, that region 20 immediately adjacent to the neck portion 14 of the implant is maintained smooth so that when the remodeling phase is completed, there will be little or no roughened implant surface exposed to the soft tissue under the dental restoration that is supported on the implant. The exact dimensions of the smooth region 20 cannot be precisely established for all cases. A length corresponding to about one turn of the screw thread is suitable for many cases, but up to three threads may be left smooth.

## CLAIMS

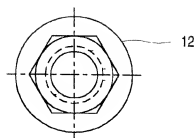
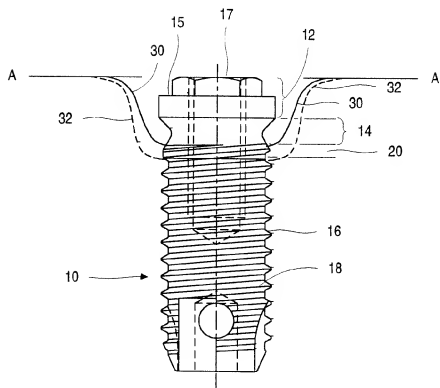
1. A dental implant having a head portion, a neck portion, and a threaded portion for  
2 contact with bone wherein said head and neck portions are provided with a smooth surface  
for blocking infection and said threaded portion is roughened to promote osseointegration  
4 with bone while leaving at least one thread adjacent said neck portion smooth and  
unroughened.
2. A dental implant of claim 1 wherein up to three threads adjacent said neck portion  
2 are left smooth.
3. A dental implant of claim 1 wherein a length of about 3 mm of said implant  
2 including said head, neck, and adjacent threaded portions is left smooth.
4. A dental implant of claim 1 wherein the head, neck, and threaded portions left  
2 smooth have a surface created by machining.
5. A dental implant of claim 1 wherein said implant is titanium or a titanium alloy and  
2 said roughness is created by a two-stop process in which the native oxide is removed by  
contact with an aqueous hydrofluoric acid solution and followed by etching of the resulting  
4 surface with a mixture of sulfuric and hydrochloric acids.
6. A dental implant comprising  
2 (a) a roughened bottom portion for facilitating osseointegration with bone;  
(b) a smooth neck portion adjacent said roughened portion for contact with  
4 gingival tissue; and  
(c) a smooth head portion adjacent said neck portion for receiving a dental  
6 restoration; wherein said roughened portion of (a) is threaded and at least one thread  
adjacent said neck portion is left smooth and unroughened.
7. A dental implant of claim 6 wherein up to three threads adjacent said neck portion  
2 are left smooth and unroughened.

8. A dental implant of claim 6 wherein the length of said head, neck, and smooth  
2 threads is a total of about 3 mm.
9. A dental implant of claim 6 wherein the head, neck, and threaded portions left  
2 smooth have a surface created by machining.
10. A dental implant of claim 6 wherein said implant is titanium or titanium alloy and  
2 said roughness is created by a two-step process in which the native oxide is removed by  
contact with aqueous hydrofluoric acid solution and followed by etching of the resulting  
4 surface with a mixture of sulfuric and hydrochloric acids.



## ABSTRACT

An infection-blocking dental implant in which a threaded portion which contacts bone is roughened except for up to three threads which may be exposed by bone recession after implantation, which have a smooth surface . Preferably, the implant is of titanium or titanium alloy and the threaded portion is roughened by a two-step acid treatment.

*FIG. 2**FIG. 1*